02-08-02 #10/068,33

2/5/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
Washington, D.C. 20231

In re PATENT APPLICATION of
Inventors: **ALLEN et al.**
Appln. No.: **09/815,937**
Filed: **March 22, 2001**
Title: **Transgenic Mice Containing Lymphoid-Specific GPCR Gene Disruptions**

Group Art Unit: **1633**
Examiner: **Qian, C. X.**
Docket/Order #. **R-611**
Deposit Acct **50-1271**
Customer # **26619**

Date: **February 4, 2002**

RESTRICTION REQUIREMENT TRANSMITTAL

Sir:

Please file the enclosed response to restriction requirement in the above-identified application. The signature below is to be treated as the signature to the enclosure in absence of a signature thereto.

FEE REQUIREMENTS FOR CLAIMS AS AMENDED

1. Small Entity previously claimed	Claims remaining	Highest # paid for		Present Extra	Small Entity	Add'l Fee	Fee Code
2. Total Claims	20	minus	49 =	0	x $9. =	+ 0	203
3. Independent Claims	08	minus	17 =	0	x 42. =	+ 0	202
4. If amendment enters multiple dependent claim(s) for the first ..... add					+ $140. =	+ 0	204
5. Original due date: January 3, 2002							
6. **Petition is hereby made** to extend the due date to cover the date this response is filed, for which the requisite fee is enclosed					**1 mo $55** 2mos $200 3mos $460 =		215 216 217
7. Enter any previous extension fee paid and (subtract)					-		
8. Total fee for extension of time:						**+$55**	
9. If Terminal Disclaimer is enclosed, add Rule 20(d) official fee					+ $55. =	+	248
10. If IDS enclosed requires Official Fee, ... add or if Rule 97(d) Petition, ... add					+ $180. = + $130. =	+ +	126 122
11. After-Final Request Fee per Rules 129(a) and 17(r)					+ $370. =	+	246
12. No. of additional inventions for examination per Rule 129(b): ..... ea					x $370. =	+	249
13. Petition fee for						+	
TOTAL FEE: ☒ **CHARGE AUTHORIZATION** ☐ **ENCLOSED** =						**$55**	

Charge Statement: The Commissioner is hereby authorized to charge any missing or insufficient fees relative to this application, or credit any overpayment, to our Account/Order Nos. above, for which purpose a duplicate copy of this sheet is enclosed.

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Express Mail Label: *EV 007607775 US*
Date of Deposit: *February 4, 2002*

I certify that this paper and listed enclosures are being deposited with the U.S. Post Office "Express Mail Post Office to Addressee" under 37 CFR 1.10 on the above date, addressed to Commissioner for Patents, BOX AMENDMENT, Washington, D.C. 20231

Joyce Vogel

#11/508
2/15/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: ALLEN et al. Group Art Unit: 1633

Serial No.: 09/815,937 Examiner: Qian, Celine X.

Filed: March 22, 2001 Atty Docket No.: R-611

For: TRANSGENIC MICE CONTAINING LYMPHOID-SPECIFIC GPCR GENE DISRUPTIONS

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office Action mailed December 04, 2001, concerning the Examiner's restriction to the claims, Applicants hereby provisionally elect, with traverse, Invention I (claims 1-10 and 17-24), drawn to a targeting construct, a method of making said targeting construct, a cell comprising a disruption in a lymphoid-specific GPCR gene, a lymphoid-specific GPCR gene knockout non-human animal and a method of making said non-human animal.

In the restriction, the Examiner asserts that claims 1-38 are drawn to six distinct subjects, grouped as: Invention I (claims 1-10 and 17-24), drawn to a targeting construct, a method of making said targeting construct, a cell comprising a disruption in a lymphoid-specific GPCR gene, a lymphoid-specific GPCR gene knockout non-human animal and a method of making said non-human animal; Invention II (claims 11, 13, and 28-33), drawn to a method of identifying an agent that modulates lymphoid-specific GPCR gene expression; Invention III (claims 12, 14, 34 and 35), drawn to a method of identifying an agent that modulates lymphoid-specific GPCR gene function; Invention IV (claims 16 and 38), drawn to an agent that modulates lymphoid-specific GPCR gene expression or function; Invention V (claims 25-27, 36 and 37), drawn to a method of identifying an agent that ameliorates cellular infiltration; and Invention VI (claim 38), drawn to an agent that ameliorates cellular infiltration. The Examiner also asserts that claim 15 is generic

to groups II and III and that claim 38 is generic to groups IV and VI. Applicants respectfully request reconsideration and withdrawal of the requirement.

Specifically, the Examiner asserts that the claims of Invention I and Invention II are patentably distinct in that the inventions are drawn to materially different compositions and methods that require different starting materials and modes of operations. The Applicants disagree with the Examiner's conclusion in that the claims of Invention I are related to the methods of Invention II. Therefore, a separate search or examination that would seriously burden the Examiner would not be required.

The Examiner also asserts that the claims of Invention I and Invention III are patentably distinct in that the inventions are drawn to materially different compositions and methods that require different starting materials and modes of operation. The Applicants disagree with the Examiner's conclusion in that the compositions and methods recited in the claims of Invention I are related to the methods recited in the claims of Invention III. A search and examination of these claims, therefore, can be made without serious burden to the Examiner.

It is also asserted by the Examiner that the claims of Invention I and Invention IV are patentably distinct in that the inventions are drawn to materially different compositions and methods that are not directly related. The Applicants disagree with the Examiner's conclusion in that the claims of Invention I are related to the lymphoid-specific GPCR expression or function modulator recited in the claims of Invention IV. A search and examination of these claims, therefore, can be made without additional burden on the Examiner.

The Examiner also asserts that the claims of Invention I and Invention V are patentably distinct in that the inventions are drawn to materially different compositions and methods that require different starting materials and modes of operation. The Applicants disagree with the Examiner's assertion in that the claims of Invention I are related to the methods recited in the claims of Invention V. Thus, a separate search or examination of these claims that would seriously burden the Examiner would not be required.

The Examiner further asserts that the claims of Invention I and Invention VI are patentably distinct in that the inventions are drawn to materially different compositions and methods that are not directly related. The Applicants disagree with the Examiner's assertion in that the compositions and methods recited in the claims of Invention I are related to the agent

recited in the claims of Invention VI. A search and examination of these claims, therefore, can be made without serious burden to the Examiner.

The Examiner also asserts that the claims of Invention II and Invention III are patentably distinct in that the inventions are drawn to methods that require different starting materials and modes of operation. The Applicants disagree with the Examiner's assertion in that the methods recited in the claims of Invention II and the methods recited in the claims of Invention III require the same starting materials and the same or related modes of operation. More particularly, claims 11 and 28-30 of Invention II and claim 12 of Invention III both require that a non-human transgenic animal comprising a disruption in a lymphoid-specific GPCR gene be provided. The claims also recite modulation of the gene by an agent. Any search or examination of the prior art conducted on these aspects, *i.e.* a non-human transgenic animal comprising a disruption in a lymphoid-specific GPCR gene and modulation of this gene, would produce results that would comprise modulation of the expression or modulation of the function of a lymphoid-specific GPCR gene. The same applies to claim 13 of Invention II and claim 14 of Invention III as directed to cells and the modulation of the expression and function of a lymphoid-specific GPCR gene.

Both claims 31-33 of Invention II and claims 34-35 of Invention III require cells comprising a disruption in a lymphoid-specific GPCR gene. In addition, both groups of claims are directed to methods of identifying agents that modulate a lymphoid-specific GPCR gene. Furthermore, both groups of claims are directed to agents that modulate a phenotype associated with a disruption in a lymphoid-specific GPCR gene. Any search or examination of the prior art conducted on these aspects would produce results that would comprise modulation of the expression or function of a lymphoid-specific GPCR gene, including modulation of a phenotype associated with a disruption in this gene. Thus, the additional burden of a separate search or examination would not be required.

With respect to Invention II and Invention IV, related as process of making and product made, respectively, the Examiner asserts that the inventions are patentably distinct in because the agent of Invention IV can be identified by a method other than the methods recited in the claims of Invention II. The Applicants disagree in that the agents recited in the claims of Invention IV

are related to the methods recited in the claims of Invention II. A search and examination of these claims, therefore, can be made without additional burden on the Examiner.

The Examiner asserts that the claims of Invention II and Invention V are patentably distinct in that the inventions are drawn to methods that require different starting materials and modes of operations. The Applicants disagree with the Examiner's conclusion. Specifically, the methods recited in the claims of Invention II and the methods recited in the claims of Invention V require the same or similar starting materials. More particularly, both groups of claims recite administering an agent to a transgenic mouse comprising a disruption in a lymphoid-specific GPCR gene. Moreover, the methods recited in the claims of Inventions II and V require the same or closely related modes of operation. For example, the methods recited in claims 28-33 of Invention II comprise the step of determining whether the agent modulates lymphoid-specific GPCR expression, wherein the agent modulates a phenotype associated with a disruption in a lymphoid-specific GPCR gene, such as cellular infiltration. This aspect of claims 28-33 is closely related to the step of determining whether the agent ameliorates cellular infiltration as recited in the method of claim 25. Therefore, a search and examination of these claims can be made without serious burden to the Examiner.

The Examiner further asserts that the claims of Invention II and Invention VI are patentably distinct in that the inventions are drawn to methods and compositions that are not directly related and that the methods of Invention II cannot produce the agents of Invention VI. The Applicants disagree with this assertion in that the method of identifying an agent that modulates lymphoid-specific GPCR expression comprising the step of determining whether the agent modulates lymphoid GPCR expression, wherein the agent modulates a phenotype as recited in claims 28 and 31 of Invention II can produce the agent recited in claim 38 of Invention VI, and thus the inventions are directly related. Thus, a search and examination of the claims of Inventions II and VI can be made without serious burden on the Examiner.

The Examiner asserts that the claims of Invention III and Invention IV, related as process of making and product made, respectively, are patentably distinct because the agents of Invention IV can be identified by a method other than the methods of Invention III. The Applicants disagree with the Examiner's assertion in that the agents of Invention IV are related to the

methods recited in the claims of Invention III. A search and examination of the claims, therefore, can be made without serious burden on the Examiner.

The Examiner also asserts that the claims of Invention III and Invention V are patentably distinct as the inventions are drawn to methods that require different starting materials and modes of operation. The Applicants disagree with the Examiner's assertion in that the methods recited in the claims of Invention III and the methods recited in the claims of Invention V require the same or similar starting materials. Further, the claims of Invention III and Invention V are drawn to methods of identifying an agent that modulates a lymphoid-specific GPCR gene, in which the steps or modes of operation of determining whether the agent modulates a lymphoid-specific GPCR gene are the same or closely related, for example, both groups of claims recite modulation of a phenotype. In the case of claim 34 of Invention III and claims 25 and 37 of Invention V, cellular infiltration is recited. However, any search or examination of the prior art should reveal results having modulation of any phenotype, including cellular infiltration. Therefore, serious burden on the Examiner would not result from a search and examination of the claims of Inventions III and V.

The Examiner further asserts that the claims of Invention III and Invention VI are patentably distinct in that the inventions are drawn to methods and compositions that are not directly related and that the methods of Invention III cannot produce the agents of Invention VI. The Applicants disagree with the Examiner's conclusion in that the methods recited in the claims of Invention III comprising the step of determining whether the agent modulates lymphoid-specific GPCR gene function, wherein the agent modulates a phenotype, *e.g.* cellular infiltration, can produce the agent that ameliorates cellular infiltration recited in the claim of Invention VI. Therefore, a search and examination of the claims can be made without serious burden on the Examiner.

The Examiner further concludes that the claims of Invention IV and Invention V are patentably distinct in that the inventions are drawn to compositions and methods that are not directly related. The Applicants disagree with the Examiner's conclusion in that the agents recited in the claims of Invention IV and the methods recited in the claims of Invention V are related. Therefore, a search and examination of these claims can be made without serious burden on the Examiner.

The Examiner also concludes that the claims of Invention IV and Invention VI are patentably distinct in that the inventions are drawn to materially distinct compositions. The Applicants disagree with the Examiner's conclusion in that the agents recited in the claims of Invention IV and the agent recited in claim 38 of Invention VI are related. A search and examination of these claims can be made without serious burden to the Examiner.

Finally, with respect to the claims of Invention V and Invention VI, related as process of making and product made, respectively, the Examiner concludes that the inventions are patentably distinct because the agent of Invention VI can be identified by a method other than the methods recited in the claims of Invention V. The Applicants disagree with the Examiner's conclusion in that the methods of Invention V and the agent of Invention VI are related. Thus, a separate search or examination that would seriously burden the Examiner would not be required.

Although the Applicants have provisionally elected Invention I for the purposes of advancing prosecution of the present application, Applicants contend for the foregoing reasons that the restriction requirement is improper. Accordingly, Applicants respectfully request reconsideration and withdrawal of the requirement.

A Petition for the Extension of Time for response to the Office Action for a period of one month from January 3, 2002 up to and including February 4, 2002 is submitted concurrently herewith.

Respectfully submitted,

Date: February 4, 2002

Mariette A. Lapiz

(Signature) (Reg. No.)

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